

)	
ABBOTT LABORATORIES, an Illinois)	
Corporation,)	Civil Action No. 09 CV 1586
)	
Plaintiff,)	Judge Robert M. Dow, Jr.
)	Magistrate Judge Jeffrey Cole
vs.)	
)	
MATRIX LABORATORIES, INC.)	
MATRIX LABORATORIES, LTD.)	
MYLAN INC.)	
)	
Defendants.)	
)	

Defendants Matrix Laboratories, Inc. (“Matrix Inc.”), Matrix Laboratories, Ltd. (“Matrix Ltd.”), and Mylan Inc. (collectively, “Defendants”), by their undersigned counsel, hereby answer the Complaint of Plaintiff Abbott Laboratories (“Abbott”) as follows:

ANSWER:

1. Defendants admit the allegations set forth in paragraph 1.

2. Defendant Matrix Laboratories Inc. (“Matrix Inc.”) is a corporation organized and existing under the laws of Delaware, having its principal place of business located at 76 South Orange Ave., Suite 301, South Orange, NJ 07079. Matrix Inc. is a wholly-owned subsidiary of, and U.S. agent for, Defendant Matrix Laboratories Limited (“Matrix Ltd.”).

ANSWER:

2. Defendants admit the allegations set forth in the first sentence of paragraph 2. Defendants admit that Matrix Inc. is an indirect, wholly-owned subsidiary of, and has acted as a U.S. agent for, Defendant Matrix Ltd. Defendants deny any remaining allegations set forth in paragraph 2.

3. Matrix Ltd. is a corporation organized under the laws of India, having principal place of business located at 1-1-151/1, 4th Floor, Sai Ram Towers, Alexander Road, Secunderabad, 500 003, India.

ANSWER:

3. Defendants admit the allegations set forth in paragraph 3.

4. Defendant Mylan Inc. (formerly known as Mylan Laboratories Inc.) is a corporation organized under the laws of the Commonwealth of Pennsylvania, with a principal place of business located at 1500 Corporate Drive, Canonsburg, PA 15317. Mylan Inc., directly or through its wholly owned subsidiary (Mylan Pharmaceuticals Inc.), is in the business of manufacturing, marketing and selling generic pharmaceutical drugs for U.S. consumers. Defendant Mylan Inc. is the majority owner of, and has a controlling interest in, Matrix Ltd.

ANSWER:

4. Defendants admit the allegations set forth in the first sentence of paragraph 4. Defendants admit that Mylan Pharmaceuticals Inc. (“MPI”) is in the business of manufacturing, marketing and selling generic pharmaceutical drugs for U.S. consumers. Defendants admit that Mylan Inc. is an indirect, majority owner of, and has an indirect, controlling interest in, Matrix Ltd. Defendants deny any remaining allegations set forth in paragraph 4.

5. On information and belief, the acts of Matrix Inc. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of, Matrix Ltd. and/or Mylan Inc.

ANSWER:

5. Defendants admit that Matrix Inc. is an indirect, wholly-owned subsidiary of, and has acted as a U.S. agent for, Matrix Ltd. Defendants admit that Mylan Inc. is the indirect, majority owner of Matrix Ltd. Defendants deny any remaining allegations set forth in paragraph 5.

6. On information and belief, the acts of Matrix Ltd. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of, Matrix Inc. and/or Mylan Inc.

ANSWER:

6. Defendants admit that Matrix Inc. is an indirect, wholly-owned subsidiary of, and has acted as a U.S. agent for, Matrix Ltd. Defendants admit that Mylan Inc. is the

indirect, majority owner of Matrix Ltd. Defendants deny any remaining allegations set forth in paragraph 6.

7. On information and belief, the acts of Mylan Inc. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of, Matrix Inc. and/or Matrix Ltd.

ANSWER:

7. Defendants admit that Matrix Inc. is an indirect, wholly-owned subsidiary of, and has acted as a U.S. agent for, Matrix Ltd. Defendants admit that Mylan Inc. is the indirect, majority owner of Matrix Ltd. Defendants deny any remaining allegations set forth in paragraph 7.

8. This is a civil action for patent infringement of United States Patent Number 7,148,359 B2 (“the ‘359 patent”) and United States Patent Number 7,364,752 B1 (“the ‘752 patent”), arising under the United States Patent Laws, Title 35, United States Code, §100, *et seq.*, and in particular under 35 U.S.C. § 271(e). This action relates to Abbreviated New Drug Application (“ANDA”) No. 91-202, which Mylan Inc., Matrix Ltd., and Matrix Inc. filed or caused to be filed under 21 U.S.C. § 355(j) with the United States Food and Drug Administration (“FDA”) for approval to market a generic copy of Abbott’s successful Kaletra[®] tablets that are sold in the United States.

ANSWER:

8. Defendants admit that Abbott’s Complaint purports to assert claims for patent infringement of United States Patent Number 7,148,359 B2 (“the ‘359 patent”) and United States Patent Number 7,364,752 B1 (“the ‘752 patent”) arising under the United

States Patent Laws in connection with the filing of ANDA No. 91-202 by Matrix Inc., seeking FDA approval to market a generic version of Kaletra tablets in the United States. Defendants deny any remaining allegations set forth in paragraph 8.

9. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

ANSWER:

9. Paragraph 9 contains legal conclusions as to which no answer is required. To the extent an answer is deemed to be required, Defendants admit that this Court has subject matter jurisdiction over this action.

10. This Court has personal jurisdiction over each of the Defendants.

ANSWER:

10. Paragraph 10 contains legal conclusions to which no answer is required. To the extent an answer is deemed to be required, Defendants do not contest this Court's exercise of personal jurisdiction over them in the Northern District of Illinois for the purpose of this action only.

11. Matrix Ltd. formulates, develops, manufactures, and sells active pharmaceutical ingredients (API), solid oral dosage forms, pharmaceutical formulations, and/or pharmaceutical products containing such API or pharmaceutical formulations (collectively "Matrix's products"). Matrix Ltd. routinely files ANDAs and seeks FDA approval to market Matrix's products in the United States. Most of Matrix Ltd.'s manufacturing facilities are FDA-approved and it focuses its marketing efforts on regulated markets such as the U.S.

ANSWER:

11. Defendants admit the allegations in the first sentence of paragraph 11. Defendants further admit that Matrix Ltd. has FDA-approved manufacturing facilities and has filed, through its agents, ANDAs seeking FDA approval to market pharmaceutical products in the United States. Defendants deny the remaining allegations set forth in paragraph 11.

12. On information and belief, Matrix Ltd., either directly or through one or more of its wholly owned subsidiaries, agents, or distributors, sells and/or distributes a substantial volume of Matrix's products in this judicial district. On information and belief, Matrix Ltd. purposefully has conducted and continues to conduct substantial business in this judicial district, from which it has derived, directly or indirectly, substantial revenue.

ANSWER:

12. Defendants deny the allegations set forth in paragraph 12, except that they admit that certain products formulated, developed and manufactured by Matrix Ltd. have been distributed and sold by agents or distributors in the United States.

13. Matrix Inc., a wholly owned subsidiary of Matrix Ltd., directly and/or through Matrix Ltd. and/or Mylan Inc., seeks FDA approval for, markets and/or sells generic drugs throughout the United States, including Illinois and this judicial district. On information and belief, a substantial volume of pharmaceutical products for which Matrix Inc. has sought FDA approval for are marketed or sold in this judicial district. On information and belief, Matrix Inc. purposefully has conducted and continues to conduct substantial business in this judicial district, from which it has derived substantial revenue.

ANSWER:

13. Defendants admit that Matrix Inc. is an indirect, wholly owned subsidiary of Matrix Ltd. and that Matrix Inc., either directly or as an agent for Matrix Ltd., has sought FDA approval to market generic drugs throughout the United States. Defendants deny the remaining allegations set forth in paragraph 13.

14. On information and belief, this judicial district is a likely destination of products that will be manufactured and sold as a result of FDA approval of Matrix Inc.'s ANDA No. 91-202, which is the subject of this lawsuit. On information and belief, Matrix Inc.'s actions relating to ANDA No. 91-202 complained of herein were done at the direction of, with the authorization of, and with the cooperation, the participation, the assistance of, and at least in part for the benefit of, its parent companies Matrix Ltd. and/or Mylan Inc.

ANSWER:

14. Defendants lack sufficient information to form a belief as to the truth of the allegation set forth in the first sentence of paragraph 14, and therefore deny that allegation. Defendants admit that Matrix Inc. is an indirect, wholly-owned subsidiary of, and has acted as a U.S. agent for, Matrix Ltd., and that Mylan Inc. is the indirect, majority owner of Matrix Ltd. Defendants admit that Matrix Inc. filed ANDA No. 91-202 with the FDA and that ANDA No. 91-202 sought approval to market generic Lopinavir/Ritonavir tablets manufactured by Matrix Ltd. Defendants deny any remaining allegations set forth in paragraph 14.

15. Mylan Inc. is in the business of formulating, developing, manufacturing, and selling generic drugs. Mylan Inc.'s U.S. product portfolio includes approximately 180 products. Mylan Inc., either directly or through one or more of its wholly owned subsidiaries, agents, or distributors, sells and/or distributes a substantial volume of its pharmaceutical products in this judicial district. Mylan Inc. purposefully has conducted and continues to conduct substantial business in this judicial district, from which it has derived substantial revenue.

ANSWER:

15. Defendants admit that one or more of Mylan Inc.'s subsidiaries is in the business of formulating, developing, manufacturing, and selling generic drugs. Defendants deny the second sentence of paragraph 15. Defendants admit that one or more of Mylan Inc.'s subsidiaries sells or distributes pharmaceutical products in this judicial district, from which revenue is derived. Defendants deny the remaining allegations set forth in paragraph 15.

16. Mylan Pharmaceuticals Inc., a wholly owned subsidiary of Mylan Inc., currently maintains a drug distributor license issued by the State of Illinois, for the purpose of, *inter alia*, distributing Mylan Inc.'s and/or Matrix Ltd.'s products in Illinois, and in this judicial district. Mylan Inc., either directly or through one or more of its subsidiaries, owns and maintains a facility in this judicial district.

ANSWER:

16. Defendants admit that MPI is a wholly-owned subsidiary of Mylan Inc. and that MPI currently maintains a drug distributor license issued by the State of Illinois. Defendants admit that MPI distributes its products in Illinois and in this judicial district.

Defendants admit that one or more subsidiaries of Mylan Inc. owns a facility in this judicial district. Defendants deny any remaining allegations set forth in paragraph 16.

17. On information and belief, Mylan Inc., Matrix Ltd., and Matrix Inc. operate as an integrated business ultimately controlled by Mylan Inc. For example, Mylan Inc.'s website, http://www.mylan.com/our_businesses/matrix.aspx lists "Matrix" as one of "Our Businesses." Based on Mylan Inc.'s 10-Q SEC form for the period ending June 30, 2008 for the six months ended June 30, 2008, the Matrix division of Mylan Inc. reported total revenues of \$222.3 million.

ANSWER:

17. Defendants admit that Mylan Inc.'s website, http://www.mylan.com/our_businesses/matrix.aspx lists "Matrix" under the category "Our Businesses" and that Mylan Inc.'s Form 10-Q for the quarterly period ending June 30, 2008 reflected total revenues for the six months ended June 30, 2008 of \$222,255,000 for the Matrix "segment." Defendants further admit that Mylan Inc. indirectly owns a controlling interest in Matrix Ltd. and that Matrix Inc. is an indirect, wholly-owned subsidiary of Matrix Ltd. Defendants deny any remaining allegations set forth in paragraph 17.

18. On information and belief, Matrix Inc., Matrix Ltd. and/or Mylan Inc. have on more than one occasion collaborated to develop, seek FDA approval for, manufacture, import, distribute, and sell pharmaceutical products (including generic drug products manufactured and sold pursuant to approved ANDAs) in the United States, and Illinois, including this judicial district.

ANSWER:

18. Defendants admit that Matrix Inc. and one or more subsidiaries of Mylan Inc., either directly or as U.S. agents for Matrix Ltd., have sought FDA approval to market pharmaceutical products manufactured by Matrix Ltd. in the United States, including Illinois. Defendants deny any remaining allegations set forth in paragraph 18.

19. On information and belief, Matrix Inc., Matrix Ltd., and Mylan Inc. acted in concert to seek approval from the FDA to market generic copies of Abbott's Kaletra[®] tablets that are the subject of ANDA No. 91-202 throughout the United States and in this judicial district.

ANSWER:

19. Defendants admit that Matrix Inc. filed ANDA No. 91-202 seeking FDA approval to market lopinavir/ritonavir tablets in 100 mg/25 mg and 200 mg/50 mg dosage strengths manufactured by Matrix Ltd. in the United States, including in this judicial district. Defendants deny any remaining allegations set forth in paragraph 19.

20. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided or abetted, contributed to and/or participated in the commission of a tortious act of patent infringement that has led to foreseeable harm and injury to Abbott, an Illinois corporation residing in this judicial district.

ANSWER:

20. Paragraph 20 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, Defendants do not contest this Court's exercise of personal jurisdiction over them for the purpose of this action only. Defendants deny the remaining allegations in paragraph 20.

21. This Court has personal jurisdiction over each of the Defendants by virtue of, *inter alia*, their marketing and sales activities in this judicial district, including but not limited to the substantial, continuous and systematic distribution, marketing, and/or sales of pharmaceutical products to residents of this judicial district.

ANSWER:

21. Paragraph 21 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, Defendants do not contest this Court's exercise of personal jurisdiction over them for the purpose of this action only. Defendants deny the remaining allegations in paragraph 21.

22. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

ANSWER:

22. Paragraph 11 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest venue in this judicial district for the purpose of this action only.

23. Abbott is the holder of approved New Drug Application ("NDA") No. 21-906 for lopinavir/ritonavir tablets, which Abbott markets and sells under the trademark Kaletra[®]. Abbott manufactures and sells various dosage strengths of Kaletra[®] tablets in the United States under NDA No. 21-906.

ANSWER:

23. Upon information and belief, Defendants admit the allegations set forth in paragraph 23.

24. On information and belief, Mylan Inc., Matrix Ltd., and Matrix Inc. acted in concert to file with the FDA ANDA No. 91-202 under 21 U.S.C. § 355(j)(2)(B), seeking FDA approval to market two dosage strengths of lopinavir/ritonavir tablets (collectively “Matrix’s generic lopinavir/ritonavir tablets”), which are generic copies of Abbott’s Kaletra® tablets.

ANSWER:

24. Defendants admit that Matrix Inc. filed ANDA No. 91-202 seeking FDA approval to market lopinavir/ritonavir tablets in 100 mg/25 mg and 200 mg/50 mg dosage strengths manufactured by Matrix Ltd. that are generic versions of Kaletra®. Defendants deny any remaining allegations set forth in paragraph 24.

25. ANDA No. 91-202 seeks FDA approval of a pharmaceutical composition comprising ritonavir and lopinavir in 100 mg/25 mg and 200 mg/50 mg dosage strengths.

ANSWER:

25. Defendants admit that ANDA No. 91-202 seeks FDA approval to market ritonavir/lopinavir tablets in 100 mg/25 mg and 200 mg/50 mg dosage strengths.

26. On January 30, 2009, Abbott received a letter on behalf of Matrix Inc., dated January 29, 2009, purporting to be a “Notice of Paragraph IV Certification” for ANDA No. 91-202 (“Matrix’s Notice letter”) pursuant to section 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95. Matrix’s Notice Letter notified Abbott that Matrix Inc. had filed ANDA No. 91-202, seeking approval to market Matrix’s generic lopinavir/ritonavir tablets.

ANSWER:

26. Upon information and belief, Defendants admit the allegations set forth in the first sentence of paragraph 26. Defendants admit the allegations set forth in the second sentence of paragraph 26.

27. The ‘359 patent was duly and legally issued by the United States Patent and Trademark Office (“PTO”) on December 12, 2006. Abbott is the owner by assignment of the ‘359 patent and has the right to sue for infringement thereof. A true and correct copy of the ‘359 patent is attached as Exhibit A.

ANSWER:

27. Defendants admit that a copy of the ‘359 patent is attached to the Complaint as Exhibit A, but deny that this patent was legally and duly issued. Defendants further state that the assignee listed on the face of the ‘359 patent purports to be Abbott Laboratories. Defendants deny any remaining allegations set forth in paragraph 27.

28. The '752 patent was duly and legally issued by the PTO on April 29, 2008. Abbott is the owner by assignment of the '752 patent and has the right to sue for infringement thereof. A true and correct copy of the '752 patent is attached as Exhibit B.

ANSWER:

28. Defendants admit that a copy of the '752 patent is attached to the Complaint as Exhibit B, but deny that this patent was legally and duly issued. Defendants further state that the assignee listed on the face of the '752 patent purports to be Abbott Laboratories. Defendants deny any remaining allegations set forth in paragraph 28.

29. On information and belief, Mylan Inc., Matrix Ltd., and Matrix Inc. acted in concert to file ANDA No. 91-202 in order to obtain approval to market Matrix's generic lopinavir/ritonavir tablets in the United States before the expiration of the '359 patent. On information and belief, Mylan Inc., Matrix Ltd., and Matrix Inc. acted in concert to file with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '359 patent are purportedly invalid, unenforceable, or not infringed.

ANSWER:

29. Defendants admit that Matrix Inc. filed ANDA No. 91-202 seeking FDA approval to market lopinavir/ritonavir tablets in 100 mg/25 mg and 200 mg/50 mg dosage strengths manufactured by Matrix Ltd. before the expiration of the '359 and '752 patents. Defendants also admit that Matrix Inc. filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that

the claims of the '359 and '752 patents are invalid, unenforceable, or not infringed. Defendants deny any remaining allegations set forth in paragraph 29.

30. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 91-202 seeking approval for the commercial marketing of Matrix's generic lopinavir/ritonavir tablets before the expiration date of the '359 patent constitutes infringement of one or more claims of the '359 patent, either literally or under the doctrine of equivalents.

ANSWER:

30. Defendants deny the allegations set forth in paragraph 30.

31. Upon FDA approval of ANDA No. 91-202, Mylan Inc., Matrix Ltd., and Matrix Inc. will infringe one or more claims of the '359 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Matrix's generic lopinavir/ritonavir tablets, and by actively inducing others under § 271(b), unless this Court orders that the effective date of any FDA approval of ANDA No. 91-202 shall be no earlier than the expiration date of the '359 patent and any additional periods of exclusivity.

ANSWER:

31. Defendants deny the allegations set forth in paragraph 31.

32. The offering to sell, sale, and/or importation of Matrix's generic lopinavir/ritonavir tablets would actively induce infringement of at least one of the claims of the '359 patent, either literally or under the doctrine of equivalents.

ANSWER:

32. Defendants deny the allegations set forth in paragraph 32.

33. Abbott will be irreparably harmed if Mylan Inc., Matrix Ltd., and Matrix Inc. are not enjoined from infringing or actively inducing infringement of at least one claim of the '359 patent. Pursuant to 35 U.S.C. § 283, Abbott is entitled to a permanent injunction against further infringement. Abbott does not have an adequate remedy at law.

ANSWER:

33. Defendants deny the allegations set forth in paragraph 33.

34. On information and belief, Mylan Inc., Matrix Ltd., and Matrix Inc. acted in concert to file ANDA No. 91-202 in order to obtain approval to market Matrix's generic lopinavir/ritonavir tablets in the United States before the expiration of the '752 patent. On information and belief, Mylan Inc., Matrix Ltd., and Matrix Inc. acted in concert to file with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '752 patent are purportedly invalid, unenforceable, or not infringed.

ANSWER:

34. Defendants admit that Matrix Inc. filed ANDA No. 91-202 seeking FDA approval to market lopinavir/ritonavir tablets in 100 mg/25 mg and 200 mg/50 mg dosage strengths manufactured by Matrix Ltd. before the expiration of the '359 and '752 patents. Defendants also admit that Matrix Inc. filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '359 and '752 patents are invalid, unenforceable, or not infringed. Defendants deny any remaining allegations set forth in paragraph 34.

35. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 91-202 seeking approval for the commercial marketing of Matrix's generic lopinavir/ritonavir tablets before the expiration date of the '752 patent constitutes infringement of one or more claims of the '752 patent, either literally or under the doctrine of equivalents.

ANSWER:

35. Defendants deny the allegations set forth in paragraph 35.

36. Upon FDA approval of ANDA No. 91-202, Mylan Inc., Matrix Ltd., and Matrix Inc. will infringe one or more claims of the '752 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Matrix's generic lopinavir/ritonavir tablets, and by actively inducing infringement by others under § 271(b), unless this Court orders that the effective date of any FDA approval of ANDA No. 91-202 shall be no earlier than the expiration date of the '752 patent and any additional periods of exclusivity.

ANSWER:

36. Defendants deny the allegations set forth in paragraph 36.

37. On information and belief, Matrix Inc., Matrix Ltd., and/or Mylan Inc. know and intend that physicians will prescribe and patients will take Matrix's generic lopinavir/ritonavir tablets for which approval is sought in ANDA No. 91-202 to treat HIV infection, and therefore will infringe at least one claim in the '752 patent.

ANSWER:

37. Defendants admit that Matrix Inc. filed ANDA No. 91-202 seeking FDA approval to market lopinavir/ritonavir tablets in 100 mg/25 mg and 200 mg/50 mg dosage strengths manufactured by Matrix Ltd. before the expiration of the '359 and '752 patents.

Defendants deny that any distribution and sale of Defendants' lopinavir/ritonavir tablets will infringe any claim in the '752 patent. Defendants deny any remaining allegations set forth in paragraph 37.

38. On information and belief, Mylan Inc., Matrix Ltd., and Matrix Inc. had knowledge of the '752 patent and, by their promotional activities and package insert for Matrix's generic lopinavir/ritonavir tablets, know or should know that they will aid and abet another's direct infringement of at least one of the claims of the '752 patent, either literally or under the doctrine of equivalents.

ANSWER:

38. Defendants admit that they were aware of the '752 patent at the time that Matrix Inc. filed ANDA No. 91-202, but deny the remaining allegations set forth in paragraph 38.

39. The offering to sell, sale, and/or importation of Matrix's generic lopinavir/ritonavir tablets would actively induce infringement of at least one of the claims of the '752 patent, either literally or under the doctrine of equivalents.

ANSWER:

39. Defendants deny the allegations set forth in paragraph 39.

40. Abbott will be irreparably harmed if Mylan Inc., Matrix Ltd., and Matrix Inc. are not enjoined from infringing or actively inducing or contributing to infringement of at least one claim of the '752 patent. Pursuant to 35 U.S.C. § 283, Abbott is entitled to a permanent injunction against further infringement. Abbott does not have an adequate remedy at law.

ANSWER:

40. Defendants deny the allegations set forth in paragraph 40.

41. On information and belief, Mylan Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 91-202 to the FDA. On information and belief, Mylan Inc. was aware of the '359 and '752 patents when it engaged in these knowing and purposeful activities referred to above.

ANSWER:

41. Defendants admit that Mylan Inc. was aware that Matrix Inc. filed ANDA No. 91-202 seeking FDA approval to market lopinavir/ritonavir tablets in 100 mg/25 mg and 200 mg/50 mg dosage strengths manufactured by Matrix Ltd. before the expiration of the '359 and '752 patents. Defendants also admit that Mylan Inc. was aware that Matrix Inc. filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '359 and '752 patents are invalid, unenforceable, or not infringed. Defendants deny any remaining allegations set forth in paragraph 41.

42. Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), Mylan Inc. induced the infringement of the '359 and '752 patents by actively and knowingly aiding and abetting the submission to the FDA of ANDA No. 91-202. The filing of the ANDA by Mylan Inc., Matrix Ltd., and Matrix Inc. constitutes direct infringement under 35 U.S.C. § 271(e). Mylan Inc.'s active and knowing aiding and abetting Matrix Ltd. and Matrix Inc. in the filing of ANDA No. 91-202 constitutes induced infringement.

ANSWER:

42. Defendants deny the allegations set forth in paragraph 42.

43. Abbott will be substantially and irreparably harmed by Mylan Inc.'s infringing activities unless those activities are enjoined by this Court. Abbott has no adequate remedy at law.

ANSWER:

43. Defendants deny the allegations set forth in paragraph 43.

44. On information and belief, Matrix Ltd. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 91-202 to the FDA. On information and belief, Matrix Ltd. was aware of the '359 and '752 patents when it engaged in these knowing and purposeful activities referred to above.

ANSWER:

44. Defendants admit that Matrix Ltd. was aware that Matrix Inc. filed ANDA No. 91-202 seeking FDA approval to market lopinavir/ritonavir tablets in 100 mg/25 mg and 200 mg/50 mg dosage strengths manufactured by Matrix Ltd. Defendants also admit that Matrix Ltd. was aware that Matrix Inc. filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '359 and '752 patents are invalid, unenforceable, or not infringed. Defendants deny any remaining allegations set forth in paragraph 44.

45. Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), Matrix Ltd. induced the infringement of the '359 and '752 patents by actively and knowingly aiding and abetting the submission to the FDA of ANDA No. 91-202. The filing of the ANDA by Mylan Inc., Matrix Ltd., and Matrix Inc. constitutes direct infringement under 35 U.S.C. § 271(e). Matrix Ltd.'s active and knowing aiding and abetting Mylan Inc. and Matrix Inc. in the filing of ANDA No. 91-202 constitutes induced infringement.

ANSWER:

45. Defendants deny the allegations set forth in paragraph 45.

46. Abbott will be substantially and irreparably harmed by Matrix Inc.'s infringing activities unless those activities are enjoined by this Court. Abbott has no adequate remedy at law.

ANSWER:

46. Defendants deny the allegations set forth in paragraph 46.

47. Matrix Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 91-202 to the FDA. Matrix Inc. was aware of the '359 and '752 patents when it engaged in these knowing and purposeful activities referred to above.

ANSWER:

47. Defendants admit that Matrix Inc. filed ANDA No. 91-202 seeking FDA approval to market lopinavir/ritonavir tablets in 100 mg/25 mg and 200 mg/50 mg dosage strengths before the expiration of the '359 and '752 patents. Defendants also admit that Matrix Inc. filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '359 and '752

patents are invalid, unenforceable, or not infringed. Defendants deny any remaining allegations set forth in paragraph 47.

48. Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), Matrix Inc. induced the infringement of the '359 and '752 patents by actively and knowingly aiding and abetting the submission to the FDA of ANDA No. 91-202. The filing of the ANDA by Mylan Inc., Matrix Ltd., and Matrix Inc. constitutes direct infringement under 35 U.S.C. § 271(e). Matrix Inc.'s active and knowing aiding and abetting Matrix Ltd. and Mylan Inc. in the filing of ANDA No. 91-202 constitutes induced infringement.

ANSWER:

48. Defendants deny the allegations set forth in paragraph 48.

49. Abbott will be substantially and irreparably harmed by Matrix Inc.'s infringing activities unless those activities are enjoined by this Court. Abbott has no adequate remedy at law.

ANSWER:

49. Defendants deny the allegations set forth in paragraph 49.

50. Defendants further answer that any allegations in the Complaint requiring a response from Defendants not specifically admitted are denied.

51. Defendants also deny that Plaintiff is entitled to the judgment and relief prayed for in paragraphs 1 through 19 of the section of the Complaint titled "Prayer for Relief."

ADDITIONAL DEFENSES

Further responding to the Complaint, Defendants assert the following additional defenses, without admitting any allegations of the Complaint not otherwise admitted and without assuming the burden when such burden would otherwise be on Plaintiff.

First Additional Defense **(Non-Infringement of the ‘359 Patent)**

1. The manufacture, use, offer for sale, sale, or importation of the ritonavir/lopinavir products that are the subject of ANDA No. 91-202 will not infringe any valid claim of the ‘359 patent.
2. The filing of ANDA No. 91-202 has not infringed the ‘359 patent because the manufacture, use, offer for sale, sale, or importation of the ritonavir/lopinavir products that are the subject of ANDA No. 91-202 will not infringe any valid claim of the ‘359 patent.

Second Additional Defense **(Non-Infringement of the ‘752 Patent)**

3. The manufacture, use, offer for sale, sale, or importation of the ritonavir/lopinavir products that are the subject of ANDA No. 91-202 will not infringe any valid claim of the ‘752 patent.
4. The filing of ANDA No. 91-202 has not infringed the ‘752 patent because the manufacture, use, offer for sale, sale, or importation of the ritonavir/lopinavir products that are the subject of ANDA No. 91-202 will not infringe any valid claim of the ‘752 patent.

Third Additional Defense **(Invalidity of the ‘359 Patent)**

5. All asserted claims of the '359 patent, if construed to encompass the ritonavir/lopinavir products that are the subject of ANDA No. 91-202, are invalid under 35 U.S.C. §§ 102, 103 or 112.

6. By way of example and not of limitation, one or more claims of the '359 patent are invalid under 35 U.S.C. §§ 102 or 103 in view of Martin D., et al. (*Pharmaceutical Research* Supp. 13(9): S-351 PDD 7474) published in September 1996 and/or in view of Dias L. et al. (*Pharmaceutical Research* Supp. 13(9): S-351 PDD 7475) published in September 1996.

Fourth Additional Defense
(Invalidity of the '752 Patent)

7. All asserted claims of the '752 patent, if construed to encompass the ritonavir/lopinavir products that are the subject of ANDA No. 91-202, are invalid under 35 U.S.C. §§ 102, 103 or 112.

8. By way of example and not of limitation, one or more claims of the '752 patent are invalid under 35 U.S.C. §§ 102 or 103 in view of Martin D., et al. (*Pharmaceutical Research* Supp. 13(9): S-351 PDD 7474) published in September 1996 and/or in view of Sham et al. (PCT international publication WO 97/21685) published in June 1997 and/or in view of Kempf et al. (U.S. Patent No. 5,674,882) issued in October 1997 and/or in view of Al-Razzak et al. (U.S. Patent No. 5,610,193) issued in March 1997.

Fifth Additional Defense
(Failure to State a Claim)

9. To the extent the Complaint purports to allege that Defendants have infringed or will infringe the '359 patent, the Complaint fails to state a claim upon which relief can be granted.

10. To the extent the Complaint purports to allege that Defendants have infringed or will infringe the '752 patent, the Complaint fails to state a claim upon which relief can be granted.

11. To the extent the Complaint purports to allege that this case is exceptional within the meaning of 35 U.S.C. § 285 and seeks an award of attorney fees, the Complaint fails to state a claim upon which relief can be granted.

WHEREFORE, Defendants seek judgment against Plaintiff as follows:

A. That Plaintiff's Complaint, and all of its causes of action, be dismissed with prejudice;

B. That judgment be entered in favor of Defendants Mylan Inc., Matrix Laboratories, Inc. and Matrix Laboratories, Ltd., including an Order adjudging U.S. Patent Nos. 7,148,359 and 7,364,752 invalid and not infringed by Defendants; and

C. That Defendants be awarded such other and further relief as the Court deems just and proper.

Respectfully submitted,

SCHIFF HARDIN LLP

Attorneys for Defendants Matrix Laboratories, Inc.,
Matrix Laboratories, Ltd., and Mylan Inc.

Dated: May 13, 2009

By: /s/ Amethyst C. Smith
Thomas B. Quinn (ARDC #3123575)
Douglass C. Hochstetler (ARDC #6192530)
Sailesh K. Patel (ARDC #6270406)

Amethyst C. Smith (ARDC #6293820)
Schiff Hardin LLP
6600 Sears Tower
Chicago, IL 60606
(312) 258-5500
(312) 258-5600 (fax)
tquinn@schiffhardin.com
dhochstetler@schiffhardin.com

CERTIFICATE OF SERVICE

I, Amethyst C. Smith, certify that on May 13, 2009, I caused to be electronically filed a copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing to all counsel of record.

/s/ Amethyst C. Smith

*Attorneys for Defendants Matrix
Laboratories, Inc., Matrix Laboratories,
Ltd., and Mylan Inc.*

SCHIFF HARDIN LLP

Thomas B. Quinn (ARDC #3123575)
Douglass C. Hochstetler (ARDC #6192530)
Sailesh K. Patel (ARDC #6270406)
Amethyst C. Smith (ARDC #6293820)
Jason G. Harp (ARDC # 6256056)
6600 Sears Tower
Chicago, IL 60606
Tel: 312 258-5500
Fax: 312 258-5600
dhochstetler@schiffhardin.com
tquinn@schiffhardin.com